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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,369	07/05/2005	Takeshi Yokoi	18969	8936

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EXAMINER	
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3739	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,369	YOKOI ET AL.	
	Examiner	Art Unit	
	SAMUEL CANDLER	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/29/2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-29 and 31-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-29 and 31-43* is/are rejected.

7)☒ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 July 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/05/2005, 06/21/2006, 07/09/2007, 09/13/2007, 03/04/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of claims 21-29 in the reply filed on 10/29/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Response to Amendment

2. This office action is responsive to the amendment filed on 10/29//2008. As directed by the amendment: claims 31-43 have been amended and claims 30 and 44-46 have been cancelled. Claims 21-29 and 31-43 are presently pending in the application.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the 'motor' must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

4. Claim 26 is objected to because of the following informalities: On line 4, the claim cites 'a rotating magnetic held.' This should be changed to a ‘rotating magnetic field.' Appropriate correction is required.

5. Claim 36 is objected to because of the following informalities: On line 3, the claim cites 'a rising and a *failing* angle.' This should be changed to 'a rising and a *falling* angle.' Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 21-22, 32-35 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Ciccolella et al (U.S. Patent No. 6,224,608).

8. Re claim 21, Ciccolella et al discloses a body cavity insertion portion 10 (see col. 4 lines 44-61; Figure 3) which is inserted into a body and which has a thrust-generating

spiral projected portion 70 (see col. 7 lines 54-60; Figure 5A) in contact with a body cavity, a rotating device 64 (see col. 5 lines 36-39; Figure 5A) for rotating the thrust-generating spiral projected portion, wherein the thrust-generating spiral projected portion is set to have a shape with a projection height not less than 0.3 mm to not more than 3 mm (see col. 3 lines 7-30).

9. Re claim 22, while Ciccolella et al does not explicitly disclose a rotational speed for his device, if the device is rotated by hand, it inherently has the capability of rotating at any speed – including a speed of not more than 5 rotations per second.

10. Re claims 32-34, while Ciccolella et al does not explicitly disclose a torque value to rotate the device, if the device is rotated by hand, it inherently has the capability of having any torque value applied to it - including a torque in the range of 0.06 cNm to not more than 1cNm.

11. Re claim 35, Ciccolella et al discloses a sheath formed by a body cavity inserting portion 10 (see col. 8 lines 11-22; Figure 3) that, as broadly as claimed, can be considered a 'capsule medical apparatus.'

12. Re claim 37, Ciccolella et al discloses the thrust-generating spiral project portion has an outer diameter of not more than 18 mm (see col. 3 lines 7-30 and col. 6 lines 9-13).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 21, 23-28, 31-33, 39-40 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yokoi et al (U.S. PGPub 2003/0181788) in view of Ciccolella et al.

15. Re claims 21 and 27, Yokoi et al discloses a capsule medical device 1 (see paragraph [0064]; Figure 3A) which is inserted into a body and which has a thrust-generating spiral projected portion 37b (see paragraph [0090]; Figure 3A) in contact with a body cavity, a rotating device 36 (see paragraph [0079]; Figure 3A) for rotating the thrust-generating spiral project portion, but Yokoi et al fails to disclose the details of the projection height of the thrust-generating spiral projected portion. One of ordinary skill in the art would have to turn to the prior art for the details. Ciccolella et al teaches a thrust-generating spiral projected portion with a projection height not less than 0.3 mm to not more than 3 mm (see col. 3 lines 7-30). Therefore, it would have been obvious to one of ordinary skill in the art to 'fill in the gaps' of the device of Yokoi et al with the details of the device of Ciccolella et al.

16. Re claim 23, Yokoi et al discloses wherein the thrust-generating spiral projected portion is formed in a multi-spiral screw shape not having less than two spirals (see paragraph [0146]; Figure 13C).

17. Re claim 24, Yokoi et al discloses wherein the thrust-generating spiral projected portion has a cross sectional shape of at least one of a circle (see Figure 7B), a semicircle and a generally R shape.

18. Re claim 25, Yokoi et al discloses wherein the thrust-generating spiral projected portion is non-continuously formed (see Figure 13C).

19. Re claim 26, Yokoi et al discloses a magnet provided in the body cavity inserting portion 36 (see paragraph [0079]; Figure 3A) and a magnetic field generating device 5 (see paragraph [0065]; Figure 1) for generating a rotating magnetic field, the magnetic field generating device being provided outside of the body.

20. Re claim 28, Yokoi et al discloses the body cavity inserting portion includes a flexible stick portion 75 (see paragraph [0128]; Figure 5A) and the thrust-generating spiral projected portion is supported rotatably with respect to the flexible stick portion.

21. Re claim 31, Yokoi et al discloses the thrust-generating spiral projected portion is formed in a multi-spiral screw shape having not more than 10 spirals (see Figure 3A).

22. Re claims 32-33, Yokoi et al discloses that the torque generated by the rotating device can be controlled by various means including data arbitrarily input (see paragraphs [0065]-[0069]).

23. Re claims 39-40, Yokoi et al discloses that the thrust-generating spiral projected portion is formed of elastic rubber and detachably attached to the body cavity inserting portion (see paragraph [0120]).

24. Re claim 43, Yokoi et al discloses a center of gravity of the body cavity insertion portion substantially matches a longitudinal central axis of the body cavity insertion portion (see Abstract).

25. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yokoi et al in view of Ciccolella et in and in further view of Gilad et al (U.S. PGPub

2005/0143644). The combined references disclose all of the claimed elements except for a motor as a rotating device and the thrust-generating spiral projected portion is rotated by the motor. Yokoi et al discloses a method of actuating a thrust-generating spiral projected portion but does not disclose this method using a motor. Gilad et al teaches using a motor 44 to rotate a capsule endoscope and alternately using an external magnetic field in combination with a magnet in the capsule to perform the rotating operation (see paragraphs [0019] and [0023]; Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device in the combined references, such that a motor can alternately be used to rotate the capsule endoscope in place of the external magnetic field and magnet, as taught by Gilad et al, to provide suitably interchangeable devices for rotating a capsule endoscope.

26. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ciccolella et al in view of Dreyfuss (U.S. PGPub 2003/0065361). Ciccolella et al discloses a thrust-generating spiral projected portion inherently possessing a rising angle and a falling angle but does not disclose the details of these angles. Dreyfuss teaches a threaded portion of a medical device to be anchored inside of the body that possesses at least one of a rising angle and a falling angle at an end portion of the spiral of not more than 45 degrees (see paragraph [0030]; Figure 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device in Ciccolella's reference, such that a thrust-generating spiral projected portion possesses at least one of a rising angle and a falling angle at an end portion of

the spiral of not more than 45 degrees, as taught and suggested above by Dreyfuss, for the purpose of having an ideally designed threaded portion for stably anchoring inside of a body.

27. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yokoi et al (U.S. PGPub 2003/0181788 – referred to below as Yokoi et al 1788) in view of Ciccolella et al and in further view of Yokoi et al (U.S. PGPub 2003/0060734 – referred to below as Yokoi et al 0734). Yokoi et al 1788 and Ciccolella et al in combination disclose thrust-generating spiral projected portion but fail to disclose the details of the outer diameter. One of ordinary skill in the art would have to turn to the prior art for the details. Yokoi et al 0734 teaches a capsule endoscope being able to fit inside of an esophagus 16 mm at its widest point (see Yokoi et al 0734 paragraph [0086]; Figure 4), requiring the device to be smaller than 18 mm in diameter. Therefore, it would have been obvious to one of ordinary skill in the art to 'fill in the gaps' of the device of the combined references of Yokoi et al 1788 and Ciccolella et al with the details of the device of Yokoi et al 0734.

28. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ciccolella et al in view of Saadat et al (U.S. Patent No. 5,954,714). Ciccolella et al discloses all of the claimed elements except for at least one groove formed along the spiral of the thrust-generating spiral projected portion, the groove having a depth smaller than a height of the thrust-generating spiral projected portion. Saadat et al teaches a device for securing to the interior of a body cavity having a thread 19 (see col. 3 lines 16-28; Figure 4) having a groove in between peaks 22b, 24b having a depth d2,

with a separate larger groove 36 (see col. 3 lines 39-46; Figure 4) in between threads 19 having a depth d1 which is twice that of groove depth d2. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device in Ciccolella's reference, to include at least one groove formed along the spiral of the thrust-generating spiral projected portion, the groove having a depth smaller than a height of the thrust-generating spiral projected portion, as taught and suggested above by Saadat et al, for the purpose of improving thread depth (see col. 1 lines 25-39).

29. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ciccolella et al in view of Fruh et al (U.S. PGPub 2003/0009222). Ciccolella discloses a thrust-generating spiral projected portion but does not disclose the spiral having a trapezoidal cross sectional shape. Fruh et al teaches a body implant device that has a thread 26 (see paragraph [0064]; Figure 1) with a trapezoidal cross sectional shape. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device in Ciccolella's reference, to include a spiral having a trapezoidal cross sectional shape, as taught and suggested above by Fruh et al, for the purpose of better reinforcing the wall of an insertion portion (see paragraph [0025]).

30. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ciccolella et al in view of Watson et al (U.S. PGPub 2005/0031665). Ciccolella discloses all of the claimed elements except for the spiral pitch being not less than 10 mm. Watson et al teaches a thread 92 (see paragraph [0112]; Figure 10A) for a medical device having a pitch greater than 10 mm. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device in

Ciccolella et al's reference, such that a spiral portion has a pitch not less than 10 mm , as taught and suggested above by Watson et al, for the purpose of having an ideal thread pitch for securing a device to an interior portion of a body.

Conclusion

31. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following are medical devices with thrust-generating spiral projected portions:

U.S. PGPub 2003/0229268

U.S. PGPub 2003/0020810

U.S. Patent No. 7,445,596

U.S. Patent No. 6,007,481

U.S. Patent No. 4,176,662

U.S. PGPub 2003/0167000

U.S. Patent No. 5,551,443

U.S. Patent No. 6,814,734

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAMUEL CANDLER whose telephone number is (571)270-3410. The examiner can normally be reached on Monday - Friday, 8 a.m. - 5 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. C./
Examiner, Art Unit 3739

/John P Leubecker/
Primary Examiner, AU 3739